

Remarks

The Office Action mailed October 6, 2003 has been received and reviewed. Claims 1 and 44 having been amended, the pending claims are claims 1-61. Claims 44-61 have been withdrawn from consideration by the Examiner, and claims 1-43 are currently under examination.

Claims 1 and 44 have been amended to recite an average grain size of no greater than 1.0 micron as measured on a polished surface, which is supported by the specification at, for example, page 20, lines 1-24 and page 28, lines 9-22.

Reconsideration and withdrawal of the rejections are respectfully requested.

Affirmation of Provisional Election

The Examiner issued a Restriction Requirement under 35 U.S.C. §121 in the above-identified application, grouping the claims as follows: Group I, Claims 1-43, drawn to an aluminum oxide ceramic material, and Group II, Claims 44-61, drawn to a method of making an aluminum oxide ceramic material. A provisional election to prosecute claims 1-43, Group I, was made in response to a telephone conversation between Applicants' Representative, Steven Skolnick, and Examiner Rudasil on 27 August 2003.

The provisional election to prosecute Group I is hereby affirmed with traverse. Applicants respectfully request reconsideration of the restrictions in this case and submit that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner.

Rejection under 35 U.S.C. §102

The Examiner rejected claims 1-9 and 12-13 under 35 U.S.C. §102(b) as being anticipated by a Master of Science thesis entitled *Fracture Characteristics, Hardness, and Grain Size of Five Polycrystalline Alumina Orthodontic Brackets*, Pham (Pham). The Examiner

also rejected claims 1-9 under 35 U.S.C. §102(b) as being anticipated by European Patent Application Publication No. 0 284 418 B1 (EP '418). Applicants respectfully traverse the rejections.

"[F]or anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly." M.P.E.P. §706.02.

Independent claim 1 (as amended) recites an aluminum oxide ceramic material having *an average grain size of no greater than 1.0 micron as measured on a polished surface and a Contrast Ratio value of less than about 0.7*. Applicants respectfully submit that neither of the documents cited by the Examiner teach an aluminum oxide ceramic material having *an average grain size of no greater than 1.0 micron as measured on a polished surface and a Contrast Ratio value of less than about 0.7*, as discussed herein below.

Pham

Pham discloses an investigation of "the fracture characteristics and related properties of five currently marketed alumina maxillary central incisor brackets" including "Contour (Class One) and MXi (TP)" (page ii, lines 3-7).

In the present specification, the average grain sizes of commercially available translucent alumina orthodontic brackets available under the trade designations "CONTOUR ceramic Brackets" from Class One Orthodontics, Lubbock, TX (i.e., Comparative Example D, page 25, lines 1-4) and "MXi" from TP Orthodontics, Inc., LaPorte, IN (i.e., Comparative Example E, page 25, lines 6-9) were measured on a polished surface and reported as 1.3 and 1.2 microns, respectively (Table 3, page 27). Thus, Applicants respectfully submit that Pham's recitation of CONTOUR and MXi brackets is *not a disclosure* of an aluminum oxide ceramic material having *an average grain size of no greater than 1.0 micron as measured on a polished surface*.

However, the Examiner points to page 29 of Pham, in which Table 2 lists CONTOUR and MXi as having mean "grain sizes" of 0.57 and 0.65 microns, respectively. However, as

discussed in the present specification, Pham is calculating the "mean chord length (L)" for fracture bracket halves (Pham, paragraph spanning pages 12 and 13), and apparently reporting the calculated value of the "mean chord length (L)" as the mean "grain size." Specifically, the present specification states:

It should be noted that grain sizes different than those stated above for the Comparative Examples D and E materials have been previously reported (Giao (Robert) Ngoc Pham, "Fracture Characteristics, Hardness, and Grain Size of Five Polycrystalline Alumina Orthodontic Brackets," Ohio State University Master's thesis, 1999). In that report Pham states that the "grain size" of Comparative Example D (CONTOUR) is 0.57 microns and that the "grain size" of Comparative Example E (MXi) is 0.65 microns. However, both Pham and the reference he cites describing his "grain size" measurement technique, (L.H. VanVlack, "Elements of Materials Science and Engineering," 6th Edition, 217-219, 1989) state, "The mean chord length, L, is an *index* of grain size." As noted above, this mean chord or intercept length must be multiplied by a proportionality constant to determine an actual grain size. However, Pham goes on to report this index of grain size (chord length) as the actual grain size, without multiplying by the needed proportionality constant. Furthermore, the VanVlack reference states that L is determined "by placing a random line of known length across a *polished and etched* microstructure," as was done in the technique described herein. However, Pham states, "Brackets of each brand were then notched with a diamond disk and *fractured* with a chisel. These *fractured* bracket halves were also mounted and coated with a gold-palladium film. The *fracture surface* morphology of each bracket was observed, and representative SEM photomicrographs were taken. The mean grain sizes of the five polycrystalline brackets were calculated directly from the SEM photomicrographs using a modified intercept method." The differences between examining a polished surface (as called for in the referenced standard) and a fractured surface (as Pham did), as well as Pham's failure to apply the proportionality constant, likely lead to the discrepancies in reported grain size for Comparative Examples D and E herein and in Pham's report.

Thus, Applicants respectfully submit that Pham lacks a disclosure of an aluminum oxide ceramic material having *an average grain size of no greater than 1.0 micron as measured on a*

polished surface, and respectfully submit that Pham fails to anticipate independent claim 1 (as amended) and dependent claims 2-9 and 12-13.

EP '418

EP '418 discloses "a ceramic product comprising: grains in a solid solution state comprising 0.7 to 3.0 weight % chromia balance alumina, or 0.7 to 3.0 weight % chromia and 0.05 weight % or less magnesia balance alumina, the sizes of said grains being no more than 4.0 μm , said grains having an average grain size of 2.0 μm or less" (column 2, lines 15-23). The Examiner also pointed to test piece P5, which is described in Fig. 5 as including 1.5 wt. % Cr_2O_3 and 0.05 wt. % MgO , and having <1.1 μm average grain size, with no indication as to the method used for measuring the average grain size.

Thus, EP '418 lacks a specific disclosure of an aluminum oxide ceramic material having *an average grain size of no greater than 1.0 micron as measured on a polished surface*.

Therefore, Applicants respectfully submit that EP '418 fails to anticipate present claim 1 (as amended) and dependent claims 2-9.

In view of the remarks presented herein above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §102.

Rejection under 35 U.S.C. §103

Rusin et al. in view of McLean et al.

The Examiner rejected claims 1-43 under 35 U.S.C. §103(a) as being obvious over U.S. Pat. Application Publication No. 2003/0031984 (Rusin et al.) in view of U.S. Pat. No. 3,464,837 (McLean et al.). Applicants respectfully traverse the rejection.

"To establish a *prima facie* case of obviousness . . . the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §706.02(j).

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of

obviousness.

Rusin et al. disclose “light transmissive crystalline ceramic dental mill blanks and prostheses having a Contrast Ratio value of less than about 0.7” (Abstract). “A preferred ceramic for the present invention is aluminum oxide” (page 3, paragraph 28). Although Rusin et al. state that “[s]ubmicron size particles are used” in a hot pressing sintering process known in the art (page 3, paragraph 35), they further state that “where the crystalline ceramic mill blank or prosthesis comprises aluminum oxide, . . . it is preferred that the average grain size of the aluminum oxide mill blank be in the range of about 5 to 50 micrometers, more preferably about 10 to 30 micrometers” (page 3, paragraph 29). Thus, Rusin et al. provide no guidance for one of skill in the art to select an aluminum oxide ceramic material having *an average grain size of no greater than 1.0 micron* (e.g., independent claims 1, 16, 29, and 42).

McLean et al. recite a dental material “made up of 40-70% of refractory oxide having a particle size between 200 μ m and about 10 μ m and consisting of alumina, titania, or mixtures thereof mixed with feldspar, borosilicate glass or dental porcelain” (Abstract). Thus, McLean et al. fail to disclose or suggest a translucent aluminum oxide ceramic material having *an average grain size of no greater than 1.0 micron* (e.g., independent claims 1, 16, 29, and 42).

Further, Rusin et al. in view of McLean et al. provide no motivation for one of skill in the art to modify the teachings therein to arrive at the presently claimed invention. For example, McLean et al. recite that “[t]he introduction of the refractory oxide into dental porcelains causes a reduction in light transmission since the refractive indices of the crystal and glass matrix do not match. The reduction in light transmission through an aluminous porcelain containing 40 percent by weight of recrystallised alumina (less than 53 microns) was clinically acceptable, 14 percent light transmission being obtained through a disc 1 mm. thick” (column 2, lines 28-35). Thus, Applicants respectfully submit that one of skill in the art would have no motivation to prepare an aluminum oxide ceramic material having an average grain size of no greater than 1.0 micron and a Contrast Ratio value of less than about 0.7, in view of McLean et al., who, in fact,

teach that inclusion of aluminum oxide in a dental material leads to a reduction in light transmission.

Thus, based on the remarks presented herein above, Applicants respectfully submit that independent claims 1, 16, 29, and 42, and dependent claims 2-15, 17-28, 30-41, and 43 are patentable over Rusin et al. in view of McLean et al.

EP '418

The Examiner also rejected claims 1-9 under 35 U.S.C. §103(a) as being obvious over European Patent Application Publication No. 0 284 418 B1 (EP '418). Applicants respectfully traverse the rejection.

As discussed herein above in the response to the rejection under 35 U.S.C. §102, EP' 418 lacks a specific disclosure of an aluminum oxide ceramic material having *an average grain size of no greater than 1.0 micron as measured on a polished surface* (e.g., present independent claim 1, as amended). Nevertheless, the Examiner asserted that "it would have been obvious to one skilled in the art to optimize the grain size of the ceramic material through routine experimentation to create grain sizes that are fine and uniform having a high hardness and superior light transmissibility" (page 9, lines 3-5 of the Office Action mailed October 6, 2003). Applicants respectfully disagree with the Examiner's assertion.

"A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." M.P.E.P. §2144.05(II)(B). "A *prima facie* case of obviousness may . . . be rebutted by showing that the art, in any material respect, teaches away from the claimed invention." M.P.E.P. §2144.05(III).

Applicants note that EP '418 fails to specifically teach or suggest that decreasing grain size might result in a Contrast Ratio value less than about 0.7 (e.g., present independent claim 1 as amended). Thus, Applicants respectfully submit that one of skill in the art would have no

reasonable expectation of success in preparing a translucent aluminum oxide ceramic material having a Contrast Ratio value of less than about 0.7 by decreasing the grain size disclosed in EP '418. Therefore, Applicants respectfully submit that decreasing grain size is not a result-effective variable to achieve the claimed result (e.g., a Contrast Ratio value of less than about 0.7 (e.g., independent claim 1)).

Moreover, Applicants respectfully submit that the art teaches away from the claimed invention. Applicants respectfully submit that, in fact, one of skill in the art would have an expectation of *decreasing translucency* when the *grain size of the ceramic material is decreased*. Specifically, Applicants respectfully submit that it is well known in the art that increasing the grain size of the ceramic material results in greater translucency. *See, for example*, Pham, which states that “[t]he larger the ceramic grains, the greater the translucency” (page 4, lines 21-22). However, Applicants have surprisingly found that the claimed grain size (e.g., an average grain size of no greater than 1.0 micron as measured on a polished surface), “contributes to a stronger material than conventional ceramic materials *without detrimentally affecting translucency*” (present specification at page 6, lines 4-6, emphasis added).

In view of the remarks presented herein above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §103.

Request for Rejoinder

Applicants note that the Examiner has withdrawn method claims 44-61 from consideration. Applicants respectfully request that, upon indication of an allowable product claim, method claims 44-61 be rejoined and examined pursuant to M.P.E.P. §821.04. *See, for example*, *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fec. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996).

Amendment and Response

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For: POLYCRYSTALLINE TRANSLUCENT ALUMINA-BASED CERAMIC MATERIAL, USES, AND METHODS

Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for

CASTRO et al.

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CERTIFICATE UNDER 37 CFR §1.10:

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The undersigned hereby certifies that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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